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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/783,780 | 02/20/2004 | Asa Abeliovich | 5199-70 | 6675 |

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| EXAMINER | |
|---|---|
| WANG, CHANG YU | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

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DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/783,780 | ABELIOVICH ET AL. | |
| | Examiner | Art Unit | |
| | Chang-Yu Wang | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *October 18, 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a parkin-associated complex, classified in for example class 530, subclass 350.

II. Claims 7- 10 (in part), 11, 29-30 (in part), 35-39 (in part), 40, 45-50 (in part), 51, and 54 (in part), drawn to a method for promoting ubiquitination of cyclin E in a post-mitotic neuron in vitro, classified in for example class 435, subclass 7.21.

III. Claim 20, drawn to a therapeutic composition for gene therapy, classified in for example class 514, subclass 44.

IV. Claims 24-28, drawn to a method of screening an agent that interacts with a parkin-associated complex, classified in for example class 435, subclass 7.21.

V. Claims 7-10 (in part), 12-19, 21-23, 29-30 (in part), 31-34, 35-39 (in part), 41-44, 45-50 (in part), 52-53, and 54 (in part), drawn to a method of treating neurodegeneration in a subject by decreasing cyclin E in a post-mitotic neuron, classified in for example class 514, subclass 2.

VI. Claims 55-64, drawn to a method for diagnosing neurodegeneration in a subject, classified in for example class 424, subclass 130.1.

VII. Claims 65-67, drawn to a kit for detecting neurodegeneration, classified in for example class 536, subclass 235.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and IV, Inventions IIII and V, Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed be used in a materially different process of using that product. The products as claimed in the Group VII can be used alternatively in a method of detecting other disorders associated with cyclin E, such as cancer, or other cell functions related to cyclin E, such as cell proliferation, in vitro or in vivo. In addition, the product in the Group III can be used to treat other diseases associated with the parkin-associated proteins, such as synaptic vesicle associated GTPase (CDCrel-1), a G protein-coupled receptor (Pael), a novel from of alpha-synuclein, an alpha-synuclein interacting protein synphilin-1 or a PDZ domain containing scaffolding protein CASK/Lin2. Thus, Inventions I, III, IV, V, VI, VII are patentably distinct.

4. Inventions I, IV, Inventions IIII, V, Inventions VI, VII are not related to each other. Inventions II and I, III, IV, V, VI, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this instant case, the materials, steps and outcomes in the methods of screening compounds and diagnosis in Groups II, IV, VI are different from those in the method of treating neurodegenerative diseases in the Group V and the method of

promoting ubiquitination of cyclin E in the Group II. In addition, the steps and effects are different in the method of promoting ubiquitination of cyclin E in vitro. Further, the patients in the Group V are not required by the rest of Groups. Thus, Inventions I, II, III, IV, V, VI, VII are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Election of Species***

6. This application contains claims directed to the following patentably distinct species of the claimed inventions:

i. If Group V is elected, Applicant is required under 35 U.S.C. 121 to elect a single species for disease selected from A) Alzheimer's disease, B) amyotrophic lateral sclerosis (Lou Gehrig's Disease), C) Binswanger's disease, D) Huntington's chorea, E) multiple sclerosis, F) myasthenia gravis, G) Parkinson's disease, or H) Pick's disease recited in claims 16 and 32 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7 and 31 are generic.

ii.If Group VI or Group VII is elected, Applicant is required under 35 U.S.C. 121 to elect a single species for the agent selected from A) nucleic acid or B) antibody

recited in claims 60, 61, 65 and 67 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 55 and 65 are generic.

7. The species listed above are patentably distinct for the following reasons:

8. These species are distinct because they are different diseases and molecules. For the disease, the etiology and potential molecular mechanisms contributed to these pathological conditions are different. The pathology and etiologies of Alzheimer's diseases are very different from those of multiple sclerosis or diseases listed in the claims. The patient populations in each pathological condition are also very distinct. The health status, the medication, the diagnosis, and the physiological condition in patients with Alzheimer's disease are very different from those in patients with the diseases recited in the claim. It requires different diagnoses, equipments, steps and treatments for these different groups of patients. Therefore, each species of diseases is patentably distinct. In addition, DNA and antibody differ with respect to their composition, structural feature, function and use. Thus, these species are patently distinct.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VII and a single species from groups i-ii that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

15. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
March 1, 2006

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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